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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS
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G-2 Reports' Recent Survey Finds Health Systems at the Forefront of Integrating Diagnostic Services

Almost 50 percent of health systems responding to the Washington G-2 Reports' First National Integrated Diagnostics Survey report having integrated their diagnostic services to some extent. Almost a third of respondents say that the integration is almost complete, with about two-thirds indicating partial indication. There are significant benefits to integration, according to respondents, predominantly an improvement in quality of care, more streamlined operations, improved access to data, cost savings, improved patient satisfaction, and improved relationships with physicians. Yet challenges remain. Forty percent of health systems responding to the survey say cultural differences between divisions have presented the greatest barriers to integration, followed by a lack of comprehensive IT solutions, resistance from physicians, and lack of staff support.

For a detailed analysis on the results from G-2 Reports' *First National Integrated Diagnostics Survey*, please read "*Inside the Industry*" on pp. 5-7.

LabCorp's Q2 Revenues Up 3.6% to $1.2 Billion; Monogram Acquisition Completed

LabCorp's sales strategy of targeting specialty physicians continues to be successful, as a 10.8 percent boost in esoteric volumes helped drive the company's second-quarter revenue growth up 3.6 percent to $1.2 billion, compared to the second quarter of 2008. Total volumes increased 2.4 percent, although excluding the impact of the consolidation of the Ontario, Canada, joint venture, this increase was 1.6 percent year-over-year.

The Burlington, N.C.-based testing provider also completed the acquisition of Monogram Biosciences for a total enterprise value of approximately $155 million. LabCorp CEO David King said during the second-quarter earnings call that he expects the acquisition's synergies to be realized by the fourth quarter of this year. Monogram is best known for its personalized medicine test portfolio, specifically its oncology and HIV resistance assays. *Continued on p. 2*

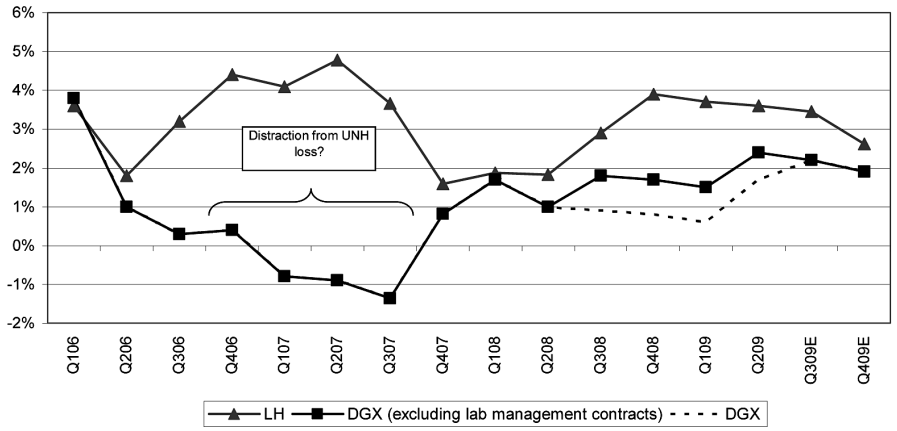
Mark Your Calendar…
LAB INSTITUTE 2009
September 23-25, 2009
Crystal Gateway Marriott
Arlington, VA

LABCORP'S Q2 REVENUES UP, *from page 1*

Drugs-of-Abuse Volumes Drag

Similar to Quest, LabCorp's drugs-of-abuse testing continues to fall—down 19 percent compared to the same period last year. Quest Diagnostics' drugs-of-abuse testing was down 24 percent for the second quarter of 2009. Quest's organic volume growth also appears to be catching up to LabCorp, according to William Blair & Co. (WB&C) analysts in Chicago (see figure). As shown in the figure, LabCorp's organic growth has outpaced Quest's organic growth over the past 18 months, particularly given the volume drag for Quest when it exited out of several lab management contracts in recent months. Nevertheless, WB&C is predicting that both lab leaders will be closer in growth rates by the end of 2009. This is due largely to the fact that while core testing volumes have been flat for the second quarter, this suggests a stabilization—but not improvement—in the decline in physician office visits related to the current recession, according to the analysts.

Estimated Organic Volume Growth for the Two National Labs (excluding drugs of abuse testing)



Growth excludes the estimated impact of extra revenue days as well as the estimated impact of the UnitedHealthcare and Aetna contract changes post Q107 as well as the decline in drugs-of-abuse testing

Source: William Blair & Co., 2009

Another challenge that LabCorp is facing is its pricing-per-accession growth, which was down 3 percent in the esoteric business this quarter. LabCorp has reported volume declines in its histology business over the past six quarters, according to a research note written by WB&C analyst Amanda Murphy. This is largely driven by more specialty physicians bringing testing in-house, as well as more competition in the specialty pathology lab landscape, including the growth of Genoptix (San Diego), and other independent labs growing their specialty pathology testing

Sonic Buys Axiom and Piedmont Medical Laboratories for $22.5 Million

Sonic Healthcare has made its first two U.S.-based acquisitions for 2009—Tampa, Fla.-based Axiom Laboratories and Piedmont Laboratories, which is based in Winchester, Va. The combined purchase price for both labs is an up-front cash payment of $20 million, in addition to a performance-based earn-out of up to $2.5 million payable over two years. The location of these labs ties in well with Sonic's other small acquisitions in Orlando, Fla., and the Washington, D.C., metro area, and cost synergies are expected to be significant.

With a combined annual revenue of $16 million—Piedmont with $11 million and Axiom with $5 million—the revenue multiple is 1.4x. This revenue multiple is a large discount compared to the price paid for large esoteric labs, which have attracted prices of greater than 2.5x, noted John Hester, an analyst with LINWAR Securities in Sydney. "Sonic's strategy of multiple small acquisitions is akin to growth by stealth," he explained. "We estimate they have completed at least eight acquisitions of pathology laboratories in the United States, each with revenues of less than $30 million in the last three years. The combined revenues of these businesses are approximately $88 million. We estimate Sonic's revenue base in the United States for fiscal year 2010 [current fiscal year] will be $616 million."

businesses. "The average price per accession is higher in histology ($122) versus genomic and other areas of esoteric testing (at $55); therefore as these volumes decline, overall esoteric PPA is also affected," wrote Murphy. "Although histology only represents 6% of LabCorp's overall business, these trends are somewhat worrying."

Nevertheless, LabCorp executives are feeling bullish about their revenue growth potential by the end of this year. Officials have updated the full-year 2009 guidance, and they expect revenue growth of 4 percent, rather than between 2 percent and 4 percent.

Quest Acquires Caritas Medical Laboratories in Boston

With hospital outreach labs making up an estimated 55 percent of the roughly $30 billion clinical lab testing market, the national labs continue to pursue alliances with these facilities in order to gain ground in the outreach market. Now Quest is gaining more of a foothold in the Boston-area outreach market, with its recently announced acquisition of the Caritas Medical Laboratories, a for-profit reference lab formerly owned and operated by Caritas Christi Health Care, the largest community-based health care system in New England. While financial details were not disclosed, the deal will also provide Caritas hospitals and affiliated physicians with access to Quest's IT capabilities.

Massachusetts' Top Hospital Outreach Labs (annual test volume)

Springfield (western region)
Baystate Medical Center 38.7M

Boston
Massachusetts General Hospital Dept. of Pathology 10.9M
Brigham and Women's Hospital 8.6M
Beth Isreal Decon Medical Center/East 4.1M

Burlington
Lahey Clinic Medical Center 5.1M

Salem
Salem Hospital Lab 4M

Source: *Laboratory Market Leaders Report 2008*, Washington G-2 Reports

The Caritas network includes five hospitals in eastern Massachusetts: St. Elizabeth's Medical Center in Brighton, Carney Hospital in Dorchester, Good Samaritan Medical Center in Brockton, Holy Family Hospital in Methuen, and Norwood Hospital in Norwood. Based on CLIA data, Caritas's annual volume for 2007 was estimated to be 1.3 million, according to Washington G-2 Reports' *Laboratory Industry Strategic Outlook 2009*.

ASCP, NCA Finalize Single Certification Agency Agreement

The American Society for Clinical Pathologists' (ASCP) Board of Registry (BOR) and the National Credentialing Agency for Laboratory Personnel (NCA) have formalized their intent to form a single certification agency as of Oct. 23, 2009. After this date, NCA will be dissolved as a corporation.

Current and active certifications will be transferred to the new agency; no examinations will be required for the transfer. Medical technologists (MT) and clinical laboratory scientists (CLS) will get a new title: medical laboratory scientist (MLS). The designation will be MLS(ASCP). In addition, clinical laboratory technicians will now be designated as medical laboratory technicians (MLT).

"It's been confusing for both employers and students and laboratory professionals in general about what exam they should take and what certification they should have," BOR Chair Kathleen Becan-McBride told *LIR*. "With this unification, we finally have clarity. Now that we have one credential that we are dealing with, that is going to be helpful in recruiting students into programs, as well as with government relations. In terms of costs to students, it will help immensely, as they will only have to take one exam now instead of two."

NCA President Susan Morris agreed that a single certification agency will simplify entry into the profession. "Likewise, employers will find it easier to set standards for entry-level competency that will ensure patient safety," she explained.

The board of governors of the new agency will be composed of five ASCP fellows (pathologists), five ASCP lab professionals, four representatives of the American Society for Clinical Laboratory Science, two representatives of the Association of Genetic Technologists, eight representatives from the eight participating societies respectively, and one public representative.

Quest Gets FDA Emergency Use Authorization for H1N1 Flu Test

Quest Diagnostics' H1N1 influenza test has received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), making the laboratory-developed test the third assay authorized by the agency since the public health emergency involving the H1N1 was declared on April 26.

Manufactured by Quest's subsidiary Focus Diagnostics, this real-time reverse transcription polymerase chain reaction (rRT-PCR) diagnostic test qualitatively detects 2009 H1N1 influenza viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, and nasal aspirates from patients with signs and symptoms of respiratory infection. Focus began performing the test in its Cypress, Calif., laboratory in May. The Centers for Disease Control and Prevention (CDC) has encouraged using the rRt-PCR H1N1 tests rather than the rapid influenza diagnostic kits currently available, such as those manufactured by Inverness Medical (Waltham, Mass.), Becton Dickinson (Franklin Lakes, N.J.), and Quidel (San Diego).

In a recent report in the CDC publication *Morbidity and Mortality Week*, the federal researchers found low sensitivity to be an issue for these rapid tests, which could detect the H1N1 virus and other viruses. However, the sensitivity was high only when the flu samples contained high concentrations of the virus.

In an EUA issued on July 24, the FDA authorized Focus to distribute the test to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity tests. Use of the test is authorized only for the duration of the declaration of emergency, which is currently set to expire on April 26, 2010.

Focus's test is the first commercial test to be granted an EUA for testing for the 2009 H1N1 flu virus. The FDA previously granted the CDC two EUAs for diagnostic tests. One EUA allows the CDC to distribute the *Continued on p. 10*

G-2 Reports Survey Finds Health Systems Leading the Way in Integrated Diagnostics

Integrated diagnostics appears to be gaining traction in many health systems and hospitals, according to results from Washington G-2 Reports' *First National Integrated Diagnostics Survey*.

Almost half (49.3 percent) of health systems responding to the survey said they have integrated their diagnostic divisions to some extent (see Table 1). Almost a third (31.2 percent) say the integration is complete while about two-thirds (68.6 percent) report the integration is partial (Table 2). Not surprisingly, laboratory (75 percent), diagnostic imaging (68.8 percent), and pathology (62.5 percent) are the diagnostic areas most commonly integrated (see Table 3), followed by cardiology (43.8 percent), orthopedic (25 percent), and pharmacy (31.3 percent). The findings are based on responses from 168 health care providers, including health systems with multiple hospitals, individual hospitals, and independent/reference labs.

In cases where the integration is partial (Table 4), the function most often integrated is information technology (91.7 percent), followed by sales and marketing (66.7 percent), operations (41.7 percent), and customer service (41.7 percent).

Forty percent of health systems responding to the survey say cultural differences between divisions have presented the greatest barriers to integration. Other barriers cited include lack of a comprehensive IT solution (26.7 percent), resistance from physicians (20 percent), and lack of buy-in from staff (13.3 percent).

"This is an exciting area with the potential to change patient diagnostics, but the challenge is to get the appropriate tools to integrate imaging with laboratory diagnostics," wrote one respondent. "Are the appropriate interfaces and IT support available to do this?"

When asked what the greatest benefits are from integration, better quality of care was cited 81.3 percent of the time, followed by streamlined operations (56.3 percent), improved access to data (43.8 percent), cost savings (31.3 percent), improved patient satisfaction (25 percent), and improved relationships with physicians (18.8 percent).

Table 1

Has Your Hospital or Health System Integrated Different Diagnostic Divisions Under a Single Umbrella?

	Yes	*No*
Health system with multiple hospitals	49.3%	50.7%
Single hospital with 1–199 beds	20.0	80.0
Single hospital with 200–399 beds	52.6	47.4
Single hospital with 400+ beds	27.3	72.7
Independent/Reference Labs	26.7	73.3
Others	25.0	75.0
Overall	37.8	62.2

Table 2

Is Integration Complete or Partial?

	Complete	*Partial*
Health system with multiple hospitals	31.3%	68.7%
Single hospital with 1–199 beds	33.3	66.7
Single hospital with 200–399 beds	50.0	50.0
Single hospital with 400+ beds	0.0	100.0
Independent/Reference labs	33.3	66.7
Others	100.0	0.0
Overall	40.6	59.4

Response Analysis by Hospital Size

In terms of individual hospitals pursuing integration of diagnostic services, midsize hospitals responding to the survey appear to be taking the lead over small and large hospitals (Table 1). More than half (52.6 percent) of single hospitals with 200-399 beds responding to the survey say they have integrated diagnostic services to some extent, while only 20 percent of hospitals with fewer than 199 beds and 27.3 percent of hospitals with 400 or more beds report integration of services.

Half (50 percent) of midsize hospitals re-

sponding to the survey say their diagnostic integration is complete (Table 2), while only a third (33.3 percent) of small hospitals report complete integration. As with health systems, individual hospitals said the divisions most commonly integrated are laboratory, imaging, pathology, cardiology, orthopedic, and pharmacy (Table 3).

All hospitals responding to the survey (100 percent) said that information technology / data was the primary function that has been integrated, with operations coming in second, and sales and marketing and customer service tying for third (Table 4).

Table 3
Divisions That Have Been Integrated

	Lab	*Imaging*	*Pathology*	*Cardiology*	*Orthopedic*	*Pharmacy*	*Other*
Health system with multiple hospitals	75.0%	68.8%	62.5%	43.8%	25.0%	31.2%	12.5%
Single hospital with 1–199 beds	33.3	66.7	66.7	33.3	0.0	33.3	0.0
Single hospital with 200–399 beds	33.3	83.3	33.3	50.0	50.0	16.7	0.0
Single hospital with 400+ beds	100.0	100.0	100.0	100.0	0.0	100.0	0.0
Independent/Reference Labs	100.0	0.0	33.3	0.0	0.0	0.0	0.0
Others	66.7	100.0	66.7	33.3	33.3	33.3	0.0
Overall	65.6	68.8	56.3	40.6	25.0	28.1	6.3

In terms of what has presented the greatest difficulty in integration of different diagnostic services, 100 percent of small hospitals say lack of a comprehensive IT solution is the biggest issue they face (Table 5), while the majority of both mid- and large-sized hospitals (66.7 percent) say cultural differences between divisions is their biggest problem, followed by lack of a comprehensive IT solution.

A significant number of midsize hospitals (80 percent) report that cost savings has been the greatest benefit from integration, followed by increased access to data (43.8 percent) and more streamlined operations (40 percent). Improved patient satisfaction, better quality of care, and improved relations with physicians all were cited 20 percent of the time. Smaller hospitals were more evenly divided over what they see as the greatest benefits from integration, with half identifying better quality of care, improved relations with physicians, and more streamlined operations.

Table 4
If the Integration Is Partial, Which Functions Have Been Integrated?

	Operations	*Sales & Marketing*	*Customer Service*	*IT/Data*
Health system with multiple hospitals	41.7%	66.7%	41.7%	91.7%
Single hospital with 1–199 beds	66.7	33.3	33.3	100.0
Single hospital with 200–399 beds	100.0	50.0	50.0	100.0
Single hospital with 400+ beds	0.0	0.0	0.0	100.0
Independent/reference labs	33.3	100.0	66.7	66.7
Overall	47.6	61.9	42.9	90.5

Clinical Laboratories' Responses

Less than a third (26.7 percent) of clinical laboratories responding to the survey say they have integrated services (Table 1), with a third of those (33.3 percent) reporting that integration is complete (Table 2).

All the labs responding to the survey say they have fully integrated their sales and marketing functions, two-thirds (66.7 percent) have integrated customer services and information technology, and one-third have integrated their operations (Table 4).

Future Plans

The majority of health systems and hospitals that have not already integrated their diagnostic services indicate that they have no plans to do so in the future. Overall, only 23.5 percent of respondents say they plan to integrate diagnostic services in the future, while 76.5 percent report that there are no plans to integrate diagnostic services. "We are a 41 hospital [integrated delivery network] located in California, Arizona, and Nevada," said one participant. "We definitely feel this issue is being pushed by Siemens with little to no interest from either lab or radiology—at least in community hospitals. Academia is different."

Table 5
What Has Presented the Greatest Difficulty in Integration of Different Diagnostic Services?

	Lack of Buy-In From Staff	*Resistance From Physicians*	*Cultural Differences*	*Lack of Comprehensive IT Solution*
Health system with multiple hospitals	13.3%	20.0%	40.0%	26.7%
Single hospital with 1–199 beds	0.0	0.0	0.0	100.0
Single hospital with 200–399 beds	0.0	0.0	66.7	33.3
Single hospital with 400+ beds	N/A	N/A	N/A	N/A
Independent/Reference labs	0.0	0.0	66.7	33.3
Overall	7.7	11.5	46.2	34.6

Half of health systems with multiple hospitals (50 percent) say the timeline for integration is more than five years, with 33.3 percent saying integration is projected to occur in two to five years, and 16.7 percent projecting integration in less than a year. Overall, the greatest number of respondents that have plans to integrate in the future (42.1 percent) say they will do it in two to five years.

Less than half (40 percent) of independent and reference labs say they have future plans to integrate diagnostic services, with half of those projecting it will be two to five years before they integrate.

Survey respondents who reported that their organization considered integration of diagnostic services but decided against it say the primary reason was that it was too difficult to implement (35.7 percent) and had no clear benefit (31 percent). Culture (16.7 percent) and cost (11.9 percent) were also cited as concerns.

"It's like herding cats," wrote one respondent. "Attempts to integrate have failed because lab directors refuse to comply with directives and corporate accepts it." Yet another respondent wrote, "There have been political and organization problems with [radiologists]. They are not a group who would be at all open to this and administration is not going to push them further right now."

Several respondents said they were not convinced integration makes financial sense. "We don't see the value in it," wrote one. "The economics at this point are not clear," wrote another. "This has not really been considered," said a third. "We are a small nonprofit hospital, and no real benefit can be seen as yet."

While the outlook for integrated diagnostics may be mixed, a number of respondents indicate they are intrigued by the idea. "The concept is quite interesting and may become part of our future," wrote one. "However, being a small, public hospital system, there will be much discussion prior to embarking on a venture like this."

Armed with its Insight Dx, Clarient Takes Aim at Genomic Health's Oncotype DX

Raaj Trivedi, Vice President of Marketing, Clarient (Aliso Viejo, Calif.)

The competitive field of breast cancer prognostic assays continues to add players—all taking aim at the market current's leader, the Genomic Health's widely reimbursed Oncotype DX. The newest player is from Southern California-based Clarient, which recently launched Clarient Insight Dx, which relies on a combination of pathology risk factors and molecular markers to categorize patients as either high or low risk.

This new test is being positioned as a companion to Clarient's current test offerings that analyze molecular markers such as ER, PR, and HER2, explained Raaj Trivedi, the company's vice president of marketing. "Unlike with Genomic Health, our clients are already sending their samples to Clarient for basic breast cancer testing," he explained. "Now when they want to know about the risk for recurrence, we can address that question and they don't need to send it to another lab who may need to rework some of these markers." Another key difference is that the Insight test is run on a formalin fixed paraffin embedded sample, while some other companies require fresh sample.

Trivedi also believes that Insight's pathway-based analysis is a value-added feature of the test. This assay analyzes the estrogen pathway to determine risk for recurrence of breast cancer. "In addition to analyzing that estrogen pathway, we assess whether there are any other major alterations that could circumvent what's going on with the estrogen pathway," he explained. "Even though the estrogen pathway might appear intact, there could be some major genetic alterations that are kicking this tumor into overdrive that have nothing to do with the estrogen pathway."

A foundation of Clarient's current sales strategy for this test is targeting current customers who have ordered the Oncotype DX test in the past, but for some reason are no longer ordering it. Many of his clients report being frustrated by the lack of explanation behind the Oncotype DX's score methodology, and Trivedi believes that Insight's technology addresses these concerns. "We are using immunohistochemistry and FISH technologies, while they are using a set of PCR-based technologies," he said. "We are using technologies that oncologists and pathologists are very familiar with, and we present a report that includes pathway analysis and what is going on with the pathway supporting the score. So we feel that we have a bit more transparency to our assay."

Plan for FDA Submission

The turnaround time for the Insight Dx test is five to seven days, which is similar to another competitor—Agendia's MammaPrint test. The Amsterdam-based company recently opened a new 3,500-foot CLIA lab in Huntington Beach, Calif. Turnaround time for the MammaPrint test is typically seven days. However, at the current estimated retail price of $3,200, Clarient's price point is lower than Agendia's price of $4,200 for MammaPrint.

While the Oncotype DX is widely reimbursed by insurers, Agendia's test is only reimbursed by a handful of insurers. Clarient is working with insurers, and

officials are confident that they will receive favorable reimbursement. "We use existing technology to do the testing—a microarray using immunohistochemistry and FISH, which CMS has reimbursed in the past, and we believe will be a strong point for us in getting the reimbursement that we need," said Trivedi.

In addition to reimbursement, the company is also pursuing clearance by the Food and Drug Administration (FDA). Currently, Insight Dx falls under the agency's in vitro diagnostic multivariate assay draft guidance. The MammaPrint test is cleared by the FDA; Oncotype DX is not.

Trivedi declined to discuss volume or growth projections for the test, but he does believe growth will be bolstered by continued clinical validation. "One of the studies that we have going on right now is hopefully going to be our FDA submission data set," said Trivedi. "We are already processing samples, and as we strengthen the data behind the test, we believe our volumes will continue to ramp up accordingly."

Embracing Newfound Independence, Creighton Medical Labs Strives for 12% to 15% Growth in 2009

Omaha, Neb.-based Creighton Medical Labs has cut its affiliation with Creighton University Medical Center Hospital and is now leveraging its current anatomic pathology (AP) and clinical lab testing platforms to embrace growth in an area largely devoid of competitive pressure from the national laboratories.

"We're lucky that we are not overrun by the national laboratories, although we do face competition from Physicians Laboratory Services, which is also based in Omaha, and other hospital laboratories, including the University of Nebraska Medical Center," said Marjel Whitmore, Creighton Medical Laboratories' director of operations. "We're very diversified, though, and we contract with our competitors to do work that they can't or don't want to do."

Creighton's annual volume is approximately 1 million, and Whitmore believes that the newly independent facility can achieve a 12 percent to 15 percent volume and revenue growth rate this year, which compares to a 10 percent growth rate that the lab had been experiencing in the academic hospital setting. "This gave us that edge to do what we really wanted to do and grow our business plan," said Whitmore. "By breaking away, you then own the instruments, can oversee the people, and you can take that and grow."

AP, IT Are Keys to Growth

Prior to January, Creighton had been buying the technical component of its reference lab work from the hospital, but it became clear that this was an unworkable relationship in order to grow the business. "It was unworkable in the sense that we had different management structure over the med techs, so we didn't have the direct supervisory authority that we needed," said Whitmore.

The clinical genomics and molecular labs were already established outside the hospital, but the other labs, including AP, flow cytometry, and microbiology, moved out last year. Creighton Medical Labs was officially independent as of Jan. 1, 2009.

Currently, there are nine different labs spread out over one large building complex on the Creighton University campus. The lab currently has 150 full-time employees, including 20 pathologists, 11 pathology residents, and two full-time sales people.

Whitmore estimates that approximately 60 percent of the labs' volume is clinical lab testing and 40 percent is AP. AP is an area for growth, but the focus right now is on launching and integrating a new LIS program from SCC Soft Computer (Clearwater, Fla.). "We have a lot of room to grow and be competitive in this area, but what is slowing us down right now in AP is that we are implementing a new software system," she explained. "Pathology is informatics, and if we are not good at getting the information out, then we are not competitive."

H1N1 FLU TEST, *from page 4*

uncleared and unapproved rRT-PCR 2009 H1N1 flu panel to public health and other qualified laboratories. This EUA was later amended to allow additional types of respiratory specimens to be tested and to allow different test components to prevent shortages. A second EUA allowed these same changes to be made to the FDA-cleared CDC rRT-PCR flu panel, which is used as the first-tier test for patient specimens with suspected 2009 H1N1 virus infection.

The FDA has not cleared or approved any tests for the identification of the 2009 H1N1 influenza virus. EUA authority allows the agency to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following a determination and declaration of emergency, provided certain criteria are met.

Expected Demand Unknown

In making this test available, Quest will be assisting public health laboratories whose capacity was stretched during the initial outbreak in April, said Focus Diagnostics' medical director Jay M. Lieberman, M.D.

Since the initial outbreak, the public health departments recognized that their primary role was in dealing with the public health aspects of this, not solely doing diagnostics. "But in the meantime, there are clinicians who want to know if their patients have infection with this virus, so they are looking to commercialize entities to be able to provide that answer, said Lieberman, who added that the company is working collaboratively with local and state public health departments. "Now when a doctor wants to know if a patient is infected with this virus, we are a resource for diagnostic testing." The results for Quest's H1N1 assay are now considered confirmed by the CDC. Previously, this confirmatory testing was only done at the CDC and public health labs.

Lieberman declined to provide estimated demand projections for this test, or even a timeline for this upcoming flu season. He did say that the testing volume that Quest has received since the virus emerged—and the number of positive test results—is unprecedented.

"Over the past 30 to 40 years, the peak flu season is most often in February, but it can start as early as October or as late as May," he explained. "But with the H1N1 virus, all of these projections are out because it's not behaving like seasonal flu, so the normal rules don't apply right now."

Lab Index Continues Strong Run; Up 10% over Five Weeks, 39% for Full Year 2009

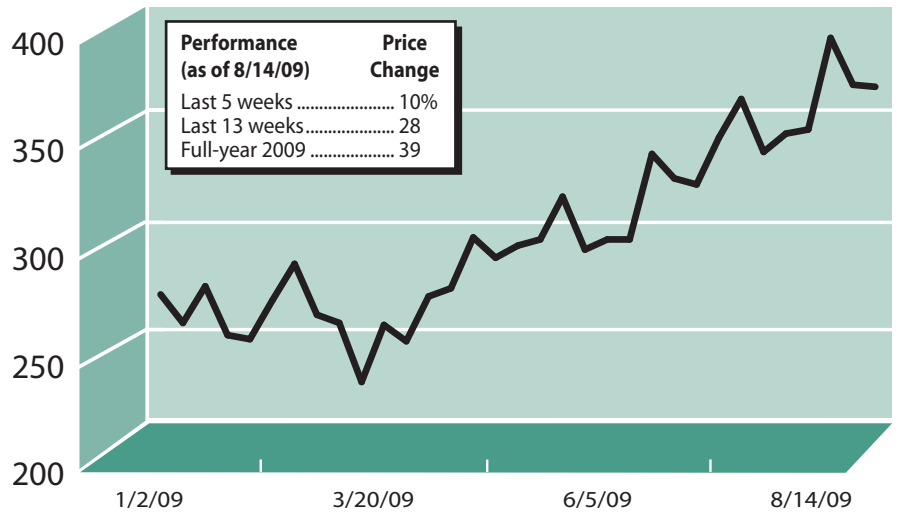
The G-2 Reports' Laboratory Stock Index's robust run continues as the summer winds down. The 13 publicly traded lab stocks tracked by the index are up 10 percent over the past five weeks, 28 percent over the past 13 weeks for the week ended Aug. 14, 2009. So far for full-year 2009, the index is up 38 percent. The Nasdaq also continues to be strong, and the S&P 500 is making impressive gains. For 2009, the Nasdaq is up over 21 percent, while the S&P 500 is up over 7 percent so far this year. Note that Monogram Biosciences (South San Francisco, Calif.) is no longer included in this monthly analysis, given its acquisition by Burlington, N.C.-based LabCorp.

Leading the gainers this month is **Orchid Cellmark**, the identity DNA testing provider based in Princeton, N.J. Orchid is up 34 percent to $2.01 per share for a market cap of $55.84 million over four weeks for the week ended Aug. 14, 2009. The second lab leading the top gains for early August is specialty testing provider **NeoGenomics** (Fort Myers, Fla.), which was up 26 percent to $1.70 per share for a market cap of $61.14 million. The list of leading top three gainers is rounded out by **Genomic Health** (Redwood City, Calif.), which is up 21 percent to $20.01 per share for a market cap of $564.45 million.

For up-to-the-minute laboratory and diagnostic firm data, financial news, and company podcasts— go to **www.g2reports.com**

There were only three labs posting losses for this period in August. Tying for first were **Psychemedics** and **Genzyme**, both down 6 percent. Acton, Mass.-based Psychemedics is down to $6.31 per share for a market cap of $33.31 million, while Cambridge, Mass.-based Genzyme is down to $50.59 per share for a market cap of $13.61 billion over the past four weeks for the week ended Aug. 14, 2009. The third lab posting a loss was U.S. testing leader **Quest Diagnostics** (Madison, N.J.), down 4 percent to $53.73 per share for a market cap of $10.11 billion.

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by *Laboratory Industry Report* from the average percentage change in the price of 14 laboratory testing service stocks.

Top Gains and Losses Over Past Four Weeks Percent price change, week ended 8/14/09

	Percent Change	Price
UP		
Orchid	34%	$2.01
NeoGenomics	26	1.70
Genomic Health	21	20.01
DOWN		
Psychemedics	6	6.31
Genzyme	6	50.59
Quest	4	53.73

INDUSTRY buzz

OIG Recommends CMS Pursue Legislation to Revamp Payment Rates for Lab Tests

Based on recent findings about the high variance in payment rates for lab tests among carriers, the Department of Health and Human Services' Office of Inspector General (OIG) is recommending the CMS request legislative authority to institute a new process for setting accurate and reasonable payment rates. This recommendation was made in a recent OIG report titled *Variation in the Clinical Laboratory Fee Schedule*.

The mandated national limit amount (NLA) that caps carrier rates is set at 74 percent of the median carrier rate for each lab test, and carriers pay labs the lower of the laboratories' charges or the capped carrier rate. The OIG found that carrier rates for nearly all lab tests varied, although 83 percent were at the NLA in 2007. One approach that OIG recommends to resolve these variances is for CMS to seek legislation to set a base payment rate for each lab tests. "If a single base payment rate for each lab tests is set, CMS should consider adjusting these rates to reflect any geographic differences in cost," states the report. A full copy of the report can be found online at http://oig.hhs.gov/oei/reports/oei-05-08-00400.pdf.

References in this issue

Agendia 714-849-7515

American Society for Clinical Pathology 800-267-2727

Bio-Reference Labs 800-229-5227

Clarient 949-425-5700

Creighton Medical Laboratories 402-280-4382

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